

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	MDL NO. 1203
_____)	
THIS DOCUMENT RELATES TO:)	
SHEILA BROWN, et al.)	
v.)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

November 14, 2007

Larry A. Rocher ("Mr. Rocher" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In April 2003, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Antoine M. Adem, M.D. Based on an echocardiogram dated February 21, 2003, Dr. Adem attested in Part II of Mr. Rocher's Green Form that he suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 40% to 49%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$462,103.³

2.(...continued)

not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement.
(continued...)

In the report of claimant's echocardiogram, Shahid Saeed, M.D., the reviewing cardiologist, stated that Mr. Rocher had "moderate [mitral regurgitation]." Dr. Saeed, however, did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Saeed calculated claimant's ejection fraction as 44%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. at § IV.B.2.c.(2)(b).

In October 2003, the Trust forwarded the claim for review by Jeremy I. Nadelmann, M.D., one of its auditing cardiologists. In audit, Dr. Nadelmann concluded that there was a reasonable medical basis for Dr. Adem's findings that claimant had moderate mitral regurgitation and a reduced ejection fraction. Thus, the Trust concedes that claimant has satisfied the criteria for Level II Matrix Benefits.

Under the Settlement Agreement, however, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered to be eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug

3.(...continued)
See Settlement Agreement § IV.B.2.c.(2)(b).

use and January 3, 2003 for a privately obtained echocardiogram, or July 3, 2003 if participating in the Screening Program.⁴ See Settlement Agreement § IV.B.1.a.; see also id. § I.22; Pretrial Order ("PTO") No. 2677 (Dec. 10, 2002).

To establish his eligibility, claimant submitted an echocardiogram that he received on July 2, 2003 under the Trust's Screening Program. Jerald Insel, M.D., completed a Gray Form⁵ that reported the results of claimant's Screening Program echocardiogram, which was submitted to the Trust.

In claimant's original Gray Form, Dr. Insel concluded that the level of mitral regurgitation could not be evaluated because claimant's Screening Program echocardiogram was "not [an] optimal study." By letter dated October 28, 2003, the Trust advised claimant that it could not reliably evaluate his July 2, 2003 Screening Program echocardiogram. The Trust's letter stated, in relevant part, the following:

The AHP Settlement Trust (the "Trust") has received a report of the results of the Transthoracic Echocardiogram that was provided to you pursuant to the Screening Program of the Nationwide Class Action Settlement Agreement with American Home Products Corporation (the "Settlement Agreement"). The physician who performed your Screening Program Transthoracic Echocardiogram has reported that a reliable

4. The Screening Program provided Transthoracic Echocardiograms and associated interpretive physician visits to eligible Class Members. See Settlement Agreement §§ I.50, IV.A.1.a, IV.A.2.b.

5. Under the Settlement Agreement, the Gray Form is used to report on the results from the Screening Program. See Settlement Agreement § VI.C.2.g.

evaluation or reading of the results could not be made on the basis of the test performed.

The Trust is required under the Settlement Agreement to make available to you one Transthoracic Echocardiogram and associated interpretive visit. The Trust did make available a Transthoracic Echocardiogram and the Trust paid for the effort to perform the procedure. Unfortunately, it did not yield a reliable and readable result.

In situations where the results of a Transthoracic Echocardiogram yield unreliable and/or unreadable results, the Trust is permitted to make determinations about your eligibility for certain benefits based on the results of a Transesophageal Echocardiogram if the Transesophageal Echocardiogram is conducted under the supervision of, and read and interpreted by, a Board-Certified Cardiologist or Board-Certified Cardiothoracic Surgeon with level 2 training in echocardiography as specified in the Recommendations of the American Society of Echocardiography Committee on Physician Training in Echocardiography. A Transesophageal Echocardiogram must be independently obtained and interpreted at the Class Member's sole expense.

There were deadlines established in the Settlement Agreement related to when results of an Echocardiogram could be submitted to the Trust. In this case, Echocardiograms performed outside the Screening Program had to be performed on or before January 3, 2003. Because this deadline has expired, if you make a second effort at getting results from an Echocardiogram by obtaining a Transesophageal Echocardiogram and wish for those results to be considered by the Trust, you can only do so if: (1) you receive a reliable and/or readable Echocardiogram evidencing an FDA positive or mild mitral diagnosis; (2) you petition the Court; (3) are able to show the Court good cause why you should be permitted to submit your Echocardiogram results after the expiration of the January 3, 2003 deadline; and (4) can

convince the Court you acted with due diligence but were unable to obtain a reliable and/or readable result from the free Echocardiogram by the appropriate deadline.

Thereafter, claimant submitted two additional Gray Forms to the Trust, signed by Dr. Adem and Randy G. Johnson, M.D., respectively, again based on claimant's Screening Program echocardiogram. In the respective Gray Forms, Dr. Adem and Dr. Johnson attested that claimant had mild mitral regurgitation. In the cover letter forwarding the additional Gray Forms to the Trust, claimant's counsel asserted that: "Dr. Adem and Dr. Johnson agree that the July 2, 2003 echo shows at least mild mitral regurgitation."

The Trust accepted the additional Gray Forms submitted by claimant as sufficient to establish claimant's eligibility under the Settlement Agreement. The Trust, however, asserted that, because the Gray Form indicated that claimant had only mild mitral regurgitation, claimant's claim for Level II Matrix Benefits had to be reduced to the B-1 Matrix pursuant to the following provisions of the Settlement Agreement:

- (2) FOR MATRIX B-1: Diet Drug Recipients who are eligible for Matrix Compensation Benefits and to whom one or more of the following conditions apply, or their Representative Claimants, will receive Matrix Compensation Benefits determined by application of Matrix B-1, provided that such Diet Drug Recipients or Representative Claimants have registered (or are deemed to have registered) for settlement benefits by Date 2:
 - (a) For claims as to the mitral valve, Diet Drug Recipients who were

diagnosed by a Qualified Physician
as having Mild Mitral Regurgitation
by an Echocardiogram performed
between the commencement of Diet
Drug use and the end of the
Screening Period (regardless of the
duration of ingestion of Pondimin®
and/or Redux™)[.]

Settlement Agreement § IV.B.2.d(2)(a).

The Trust issued a post-audit determination that Mr. Rocher was entitled only to Matrix B-1, Level II benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted letters from Dr. Johnson and A.R. Maniet, D.O., regarding claimant's Screening Program echocardiogram. Dr. Johnson stated, in relevant part, that claimant's Screening Program shows "at least, mild mitral regurgitation" and "[t]here is a very real possibility that Mr. Rocher was suffering from moderate mitral regurgitation on the date of the study, but the quality of the study prevents a definite conclusion to that effect."⁷ Dr. Maniet stated, in

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Rocher's claim.

7. Claimant's counsel also submitted an affidavit from claimant in which claimant described the circumstances under which claimant received his Screening Program echocardiogram. According to claimant, one of the technicians advised claimant that "this was her first Echo." Claimant further noted that
(continued...)

relevant part, that the level of mitral regurgitation could not be determined on claimant's Screening Program echocardiogram using the Singh criteria. Dr. Maniet opined, however, that because claimant's earlier echocardiogram of February 21, 2003 revealed moderate mitral regurgitation: "In my professional opinion, I would not expect to see a measurable change in any of the echocardiographic criteria due to the short interval between late February and early July, a period of roughly 4 months."⁸ Alternatively, claimant asserted that, because the Trust agrees that claimant's February 21, 2003 echocardiogram shows moderate mitral regurgitation, "the Trust should allow substitution of the February 21, 2003 echocardiogram for the July 2, 2003 Screening Program echocardiogram and treat the February 21, 2003 echocardiogram as timely."

The Trust then issued a final post-audit determination, again determining that Mr. Rocher was entitled only to Matrix B-1, Level II benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807, Audit Rule 18(c). The Trust

7.(...continued)

"both [technicians] seemed somewhat confused during the entire process." Claimant also stated that: "It was further my understanding that my echocardiogram was being used as a training session."

8. Claimant also submitted a report for a November 5, 2005 echocardiogram, which concluded that claimant had moderate mitral regurgitation and a reduced ejection fraction.

then applied to the court for issuance of an Order to show cause why Mr. Rocher's claim should be paid. On July 6, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6410 (July 6, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on February 5, 2007. Claimant submitted a sur-reply on February 27, 2007. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issues presented for resolution of this claim are: (1) whether claimant may establish his eligibility for Matrix Benefits through the substitution of an otherwise untimely February 21, 2003 echocardiogram for a Screening Program echocardiogram, which the Trust concluded could not be reliably evaluated; and (2) whether the Trust may rely on the same Screening Program echocardiogram as a reduction factor in the determination of Matrix Benefits.

In support of his claim, Mr. Rocher reasserts the arguments that he made in contest. Claimant also asserts that his Screening Program echocardiogram should not be used as a reduction factor because the Trust previously has concluded that it could not reliably evaluate the echocardiogram. Claimant further requested that the court permit the substitution of

claimant's February 21, 2003 echocardiogram to establish claimant's eligibility for Matrix Benefits.

In response, the Trust asserts that it lacks the authority to permit substitution of claimant's February 21, 2003 echocardiogram for claimant's Screening Program echocardiogram. The Trust also argues that claimant's claim is required to be reduced to Matrix B-1 because, according to the Trust, claimant's own physicians concede that the Screening Program echocardiogram shows mild regurgitation.

After reviewing the entire Show Cause Record, we find that claimant should be permitted to substitute his February 21, 2003 private echocardiogram for his Screening Program echocardiogram to establish his eligibility for Matrix A-1, Level II benefits and that the Screening Program echocardiogram may not be used to reduce Mr. Rocher's claim to Matrix B-1.

Class members who did not participate in the Screening Program were required to obtain a private echocardiogram that revealed mild or greater aortic or mitral regurgitation by January 3, 2003. To permit the substitution of claimant's February 21, 2003 echocardiogram to establish eligibility, the court must determine whether claimant's failure to obtain a private echocardiogram by the January 3, 2003 deadline was the result of "excusable neglect." The deadlines imposed by the Settlement Agreement may be extended if the claimant can show his or her failure to meet the deadlines was due to "excusable neglect." In In re Orthopedic Bone Screw Prods. Liab. Litig.,

246 F.3d 315, 323 (3d Cir. 2001), our Court of Appeals reiterated the Supreme Court's analysis of excusable neglect as set forth in Pioneer Inv. Servs. Co. v. Brunswick Assocs. Ltd. P'ship., 507 U.S. 380 (1993). Four factors should be evaluated when deciding whether excusable neglect exists: (1) the danger of prejudice to the nonmovant; (2) the length of the delay and its potential effect on judicial proceedings; (3) the reason for the delay, including whether it was within the reasonable control of the movant; and (4) whether the movant acted in good faith. Pioneer, 507 U.S. at 395; Bone Screw, 246 F.3d at 322-23.

Under the Pioneer criteria, claimant's conduct in attempting to obtain a proper echocardiogram to establish his eligibility constitutes excusable neglect because: (1) the Trust suffered no prejudice (and asserts no prejudice) from permitting the substitution of claimant's February 21, 2003 echocardiogram for his Screening Program echocardiogram⁹; (2) claimant's one-month delay in obtaining a private echocardiogram does not impact judicial proceedings as the Trust already has audited his claim; (3) even if there were a delay, the reason for the delay was the result of the Trust's failure to provide a proper Screening Program echocardiogram for claimant to rely on in establishing his eligibility; and (4) claimant acted in good faith by seeking the substitution in connection with this show cause proceeding.

9. The Trust only asserts that it lacks the authority to permit the substitution. Although the Trust is correct, the court, obviously, has the requisite authority.

Applying the Pioneer criteria, therefore, weighs heavily in favor of finding that claimant's actions constitute excusable neglect. Further, claimant should not be penalized for receiving a Screening Program echocardiogram that could not be reliably evaluated. Accordingly, the court will permit claimant to rely on his February 21, 2003 private echocardiogram to establish his eligibility for Matrix Benefits.

For similar reasons, the Trust may not rely on the Screening Program echocardiogram as a reduction factor to reduce claimant's claim for Level II benefits to Matrix B-1.¹⁰ As reflected in its October 23, 2003 correspondence, the Trust itself concluded that "a reliable evaluation or reading of the results" could not be made on the Screening Program echocardiogram.¹¹

10. Although the Trust attempts to rely on the additional Gray Forms submitted by claimant, we do not believe that the Gray Forms can be relied upon by the Trust to support its argument for reducing the claim to Matrix B-1. First, as noted above, the Trust consistently has maintained that it could not reliably evaluate claimant's Screening Program echocardiogram. Second, the additional Gray Forms were submitted by claimant to establish his eligibility and attempt to remedy the deficiencies of the Screening Program echocardiogram. Finally, as reflected in contemporaneous correspondence from claimant's counsel in submitting the Gray Forms to the Trust, as well as subsequent correspondence from one of claimant's physicians, claimant asserted that the Screening Program echocardiogram showed at least mild mitral regurgitation and not only mild mitral regurgitation. Under these circumstances, the Trust may not rely on the Screening Program echocardiogram for application of the Settlement Agreement's reduction factor of mild mitral regurgitation.

11. The Trust ultimately had claimant's Screening Program
(continued...)

For the foregoing reasons, we conclude that claimant is entitled to Matrix A-1, Level II Benefits. Therefore, we will reverse the Trust's denial of Mr. Rocher's claim for Matrix Benefits.

11.(...continued)
echocardiogram audited by another auditing cardiologist. Significantly, although the auditing cardiologist concluded that there was no regurgitation on claimant's Screening Program echocardiogram, the Trust is not relying on the auditing cardiologist's conclusion regarding claimant's Screening Program echocardiogram.

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PRETRIAL ORDER NO.

AND NOW, on this 14th day of November, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that claimant Larry A. Rocher is entitled to Matrix A-1, Level II Matrix Benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805.

BY THE COURT:

/s/ Harvey Bartle III

C.J.